SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Potassium Chloride 0.15% Sodium Chloride 0.18% and Glucose 4% Solution for Infusion.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride 0.15% Sodium Chloride 0.18% and Glucose 4% Solution for Infusion. has the following composition:

Name	Specification Reference	%w/v
Potassium Chloride	EP	0.15
Glucose Monohydrate for Parenteral Use	EP	4.4
(Equivalent to Anhydrous Glucose		*4.0)*
Sodium Chloride BP for Injections	EP	0.18

For a full list of excipients, see 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion

4 CLINICAL PARTICULARS.

4.1 Therapeutic indications

Potassium replacement therapy

4.2 Posology and method of administration

The volume and rate of infusion will depend upon the requirements of the individual patient and the judgement of the physician.

Adults
The rate of infusion should not exceed 10-20 mmols of potassium per hour. The total daily dosage of potassium should not exceed 200 mmols of potassium.

Children
Correspondingly reduced volumes and rates of infusion may be required.

Elderly
A reduced volume and rate of infusion may be necessary to avoid circulatory overload, particularly in patients with cardiac or renal insufficiency.

Method of Administration

Solution for Infusion

4.3 Contraindications

Addison's disease, adrenal insufficiency, acute or chronic renal disease, oliguria, anuria and patients with hyperkalaemia. The intravenous infusion of glucose solutions may also be hazardous in patients with impaired hepatic function.

4.4 Special warnings and precautions for use

Solution for infusion must be carried out slowly. Caution should be used with administration to patients receiving digitalis therapy, patients with renal or adrenal insufficiency, cardiac disease, acute dehydration or heat cramp, those receiving potassium sparing diuretics and patients with sickle cell haemoglobinopathy.

Caution should be exercised in the volume and rate of infusion since fluid overload and hyperkalaemia may compromise cardiac function. Before administering potassium by the intravenous route a non-potassium containing hydrating solution should be administered to ensure adequate renal function.

The label states: Rapid infusion may be harmful.
Do not use unless the solution is clear and free from particles.
Contains 10 mmol Potassium (500 ml)
Contains 20 mmol Potassium (1000 ml)

4.5 Interaction with other medicinal products and other forms of interaction

Care should be exercised in the concurrent administration of potassium containing intravenous solutions and potassium sparing diuretics.

ACE-inhibitors; Cyclosporin; care should be taken when administering to patients with digitalis therapy.

4.6 Fertility, pregnancy and lactation

The use of this product during pregnancy and lactation has not been assessed, but its use during these periods is not considered a hazard.

4.7 Effects on ability to drive and use machines.

Not applicable

4.8 Undesirable effects

Adverse effects are usually due to hyperkalaemia and include listlessness, mental confusion, parasthesiae, weakness, hypotension, arrhythmias and sometimes cardiac arrest. Thrombosis of the selected vein may occasionally occur.

4.9 Overdose

Symptoms of overdosage include hypotension, cardiac arrhythmias, heart block and cardiac arrest. Treatment is to stop infusion immediately and if there is persistent acidosis, administer solution for infusion for sodium bicarbonate. Hyperkalaemia may be reversed by the administration of calcium gluconate injection 10% with ECG monitoring.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Potassium chloride and sodium chloride provide essential ions to maintain the intracellular/extracellular milieu.

Glucose is a monosaccharide which provides a source of energy.

5.2 Pharmacokinetic properties

Glucose is metabolised via pyruvic or lactic acid to carbon dioxide and water with the release of energy. All body cells are capable of oxidising glucose, and it forms the principal source of energy in cellular metabolism.

5.3 Preclinical safety data

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name	Specification Reference	%w/v
Water for Injections in bulk	EP	TO 100
Hydrochloric Acid	EP	QS
Sodium Hydroxide	BP	QS

6.2 Incompatibilities

Incompatibilities have been demonstrated in potassium containing intravenous infusions with for example, amikacin, amphotericin, benzyl-penicillin and dobutamine.

Because of the nature of the plastic material of the Steriflex bag (PVC), this solution should not be used as a vehicle for the administration of drugs which may be sorbed to the surface of the bag to varying and significant degrees.

6.3 Shelf life

500 & 1000ml PVC Bags - 24 months.
500 & 1000ml Polyolefin Bags – 36 months

6.4 Special precautions for storage

Store at 2° to 25°C

6.5 Nature and contents of container

The container is a flexible 500 or 1000ml bag made of medical grade PVC.

a) A hermetically sealed polythene bag.
b) A rectangular pouch consisting of polyamide/polythene composite
c) Polyamide/Polyethylene-Propylene composite laminate welded to polypropylene ethylene propylene composite, plugged with a polycarbonate plug with either a bromobutyl (West 4481/45) or gum (West 7006/45) stopper.

Or

A flexible 500 or 1000ml polyolefine bag sealed in a polyolefine overwrap.

6.6 Special precautions for disposal

Opening the overwrap:
Locate the corner tabs at the end of the bag. Grip the two tabs and pull the two halves of the overwrap apart, releasing the bag onto a clean surface.

Setting up the solution:
Position the roller clamp of the giving-set to just below the drip chamber and close.
Hold the base of the giving set port firmly and grip the wings of the twist of tab. Twist to remove the protective cover.
Still holding the base of the giving-set port push the set spike fully into the port to ensure a leak proof connection.
Prime the set in accordance with the manufacturer's instructions.

7 MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

PL 08828/0076

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31st May 1989 / 9th November 1994

10 DATE OF REVISION OF THE TEXT

26/11/2024